* Indicates investigator responsibility

**A PROBLEM occurs that may affect individuals associated with VA research.**

**A "LOCAL" ADVERSE EVENT (AE) occurs (i.e., an AE occurs at a site for which the VA investigator's IRB of Record is responsible).**

Is the AE "SERIOUS" as defined by FDA, i.e., Did the AE result in (or need medical or surgical intervention to prevent) death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, or jeopardy to any subject's rights, safety, or welfare?

**Does the PROBLEM involve or suggest RISKS to VA research SUBJECTS?**

**Yes**

**VHA REQUIRES that the PROBLEM or AE be REPORTED to the IRB within 5 DAYS. A QUALIFIED IRB MEMBER has 5 DAYS to CATEGORIZE it."**

Was the PROBLEM or AE actually SERIOUS?

**No**

Facility has flexibility in setting requirements for reporting to the IRB.

**Yes**

DO NOT REPORT TO ORO

Was the PROBLEM or AE ANTICIPATED as to NATURE, SEVERITY, OR FREQUENCY as stated in the protocol, consent document, investigators' brochure, or other IRB-approved materials?

**Yes**

IRB CHAIR MUST REPORT TO FACILITY DIRECTOR WITHIN 5 DAYS. FACILITY MUST REPORT TO ORO RO WITHIN 5 DAYS.

**No**

Was the PROBLEM or AE RELATED or POSSIBLY RELATED to the research?

**No**

**Yes**

Was the PROBLEM or AE RELATED or POSSIBLY RELATED to the research?

**No**

**Yes**

IRB CHAIR MUST REPORT TO FACILITY DIRECTOR WITHIN 5 DAYS. FACILITY MUST REPORT TO ORO RO WITHIN 5 DAYS.

* Risks may reflect potential physical, psychological, social, or economic harm.

** See Subparagraph 6a(3).